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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,221	06/20/2001	Alan E. Moorman	C-2805/5 (PHA 4166.5)	3271

321 7590 08/13/2003

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 08/13/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,221

Applicant(s)

Moorman et al

Examiner

Shailendra Kumar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 11, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 22, 25, 31, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 22, 25, 31, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/11/03 has been entered.

Claims 1-2, 22, 25, and 31-32 are pending in this application.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-2, 22, 25 and 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain benzimidazole, does not reasonably provide enablement for millions of sulfur containing compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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For rejection under 35 U.S.C. 112 first paragraph, certain factors must be considered under the holding In re Wands, 8 USPQ 2d 1400, 1404(CAFC) 1988.

1) The nature of the invention is using sulfur containing compound which is an inhibitor of (H+/K+)ATPase and an inhibitor of a herpetoviridae protease for treatment of herpetoviridae infection. There are millions of other sulfur containing compounds, and which may or may not treat herpetoviridae infection.

2) Benzimidazole are well known in the art.

3) The level of predictability is low, as is true of most biological and chemical systems.

4) The amount of guidance provided by the applicants is minimal and is restricted to certain class of compounds belonging to benzimidazole, see pages 71-128 of the instant specification, and no disclosure is provided for any other class of compounds containing sulfur, which can be used for treating herpetoviridae infection.

5) The existence of working examples is limited to benzimidazole class of compounds, which inhibit (H+/K+)ATPase enzyme.

6) Therefore, an undue quantity of experimentation would be needed to ascertain as to which sulfur containing compounds would inhibit (H+/K+)ATPase enzyme, as well as inhibit herpetoviridae protease.

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experiment should proceed.

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Applicants claim a method of treating herpetoviridae infection in a subject by administering a sulfur containing compound which is an inhibitor of (H⁺/K⁺)ATPase and an inhibitor of a herpetoviridae protease. The teachings in the specification is limited to certain benzimidazole class of compounds, see for examples, page 71-128. However, one of ordinary skill in the art is left to speculate as to what other sulfur containing compounds might be useful for treating herpes virus, if any.

Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 22, 25 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Girjavallabhan et al(EP 0 407 217).

EP'217, page 5, line 6, and page 40, example 30, anticipates instant claims, in terms of treatment of herpetoviridae infection using sulfur containing compound. With respect to mechanism, i.e. inhibition of (H⁺/K⁺)ATPase and inhibition of herpetoviridae protease, the same is inherent.

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Claim Rejections - 35 U.S.C. § 103

6. Claims 1-2, 22, 25 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Lindberg et al and EP'217.

Lindberg et al(TIPS- October 1987) teach that benzimidazole class of compounds containing sulfur are inhibitors of (H⁺/K⁺)ATPase, see page 399, abstract, page 400, Fig. 2, and column 3. The difference between the reference and herein claimed method is that the reference does not mention herpetoviridae infection and inhibition of herpetoviridae protease.

EP'217, disclose that benzimidazole containing sulfur are know to treat herpes infection, see page 5, line 6, page 40, example 30.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the Lindberg et al compounds for treating herpes infection, as taught by EP'217, because the latter reference expressly teach that the benzimidazole class of compounds containing sulfur are known to treat herpes. As to the functionality and mechanism is concerned, inasmuch as the structure of the compounds are similar, the disease is same, it will be expected that the compounds will have same mechanism, i.e., inhibition of herpetoviridae protease.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-2, 22, 25, and 31-32 are rejected under the judicially created doctrine of double patenting over claims 1-17 of U. S. Patent No. 5,945,425 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The above patent teaches method of treating herpes virus, a DNA virus, using same compounds as disclosed in herein, viz, benzimidazole derivatives. Inasmuch as the compounds are similar, the disease is similar, the mechanism is obvious and inherent.

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Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

No claim is allowed.

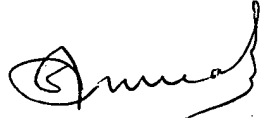
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to S.Kumar whose telephone number is (703)-308-4519. The examiner can normally be reached on Monday to Friday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.

S.Kumar

8/12/03


SHAIENDRA KUMAR
PRIMARY EXAMINER
GROUP 1200
1621